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**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

JANSSEN PHARMACEUTICALS, INC.
and JANSSEN PHARMACEUTICA NV,

Plaintiffs,

v.

TEVA PHARMACEUTICALS USA, INC.
and TEVA PHARMACEUTICALS
INDUSTRIES, LTD.,

Defendants.

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) Civil Action No. 2:18-00734
) (CCC)(MF)
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) *Electronically Filed*
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**DEFENDANTS TEVA PHARMACEUTICALS USA, INC.
AND TEVA PHARMACEUTICALS INDUSTRIES, LTD.'s
ANSWER, AFFIRMATIVE DEFENSES AND COUNTERCLAIMS**

Defendants Teva Pharmaceuticals USA, Inc. ("TPU") and Teva Pharmaceuticals Industries, Ltd. ("TPI") (collectively, "Teva" or "Defendants") through their attorneys, hereby

submits their Answer, Defenses, and Counterclaims to the Complaint filed by Plaintiffs Janssen Pharmaceuticals, Inc. (“JPI”) and Janssen Pharmaceutica NV (“JPN”) (collectively, “Janssen” or “Plaintiffs”).

ANSWER TO COMPLAINT

Each of the paragraphs below corresponds to the same-numbered paragraphs in the Complaint. Defendants deny all allegations in the Complaint, whether express or implied, that are not specifically admitted below. Any factual allegation below is admitted only as to the specific admitted facts, not as to any purported conclusions, characterizations, implications, or speculations that arguably follow from the admitted facts. Defendants deny that Plaintiffs are entitled to the relief requested or any other relief.

Defendants, through their attorneys, answer as follows:

NATURE OF THE ACTION

1. Defendants admit that the Complaint purports to state an action for patent infringement of United States Patent No. 9,439,906 (the “’906 patent”).

2. Defendants admit that the Complaint purports to state an action for patent infringement of United States Patent No. 9,439,906 (the “’906 patent”) and that said action purports to relate to the submission of an Abbreviated New Drug Application (“ANDA”) by TPU to the United State Food and Drug Administration (“FDA”) seeking approval to market a generic version of JPI’s Invega Sustenna® brand products prior to the expiration of the ‘906 patent.

THE PARTIES

3. Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations of paragraph 3.

4. Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations of paragraph 4.

5. Defendants admit that TPU is a corporation organized under the laws of the state of Delaware having a place of business at 1090 Horsham Road, North Wales, Pennsylvania 19454-1090.

6. Defendants admit that TPI is a company organized and existing under the laws of Israel, having a place of business at 5 Basel Street, Petach Tikva 49131 Israel.

7. Defendants admit that TPU is a pharmaceutical company that develops and distributes pharmaceutical products, including generic pharmaceutical products, for sale in the United States, including in this Judicial District.

8. Defendants admit that TPU is an indirect wholly-owned subsidiary of TPI.

9. Defendants deny the allegations of paragraph 9.

JURISDICTION AND VENUE

10. Defendants admit that the Complaint purports to state an action for patent infringement arising under the Patent Laws of the United States, 35 U.S.C. § 271(e)(2), including a purported action seeking declaratory judgment pursuant to the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02.

11. Paragraph 11 contains legal conclusions to which no answer is required. Defendants do not contest, for the purposes of this action only, that the Court has jurisdiction of the subject matter of this action.

12. Paragraph 12 contains legal conclusions to which no answer is required. Defendants do not contest, for the purposes of this action only, that venue is proper in this judicial district.

13. Admitted.

14. Paragraph 14 contains legal conclusions to which no answer is required. To the extent an answer is required, for purposes of this action only, TPU does not contest jurisdiction in this Court.

15. Paragraph 15 contains legal conclusions to which no answer is required. To the extent an answer is required, for purposes of this case only, TPU does not contest jurisdiction in this Court.

16. Paragraph 16 contains legal conclusions to which no answer is required. To the extent an answer is required, for purposes of this case only, TPU does not contest jurisdiction in this Court.

17. Defendants admit that TPU employs people throughout New Jersey.

18. Paragraph 18 contains legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that TPU it is registered to do business in New Jersey, that it has appointed a registered agent in New Jersey for receipt of service of process and that it is registered as a drug manufacturer and wholesaler in New Jersey.

19. Paragraph 19 contains legal conclusions to which no answer is required. To the extent an answer is required, for purposes of this case only, TPU does not contest jurisdiction in this Court.

20. Defendants admit that TPI is in the business of manufacturing generic drug products.

21. Paragraph 21 contains legal conclusions to which no answer is required.

22. Denied.

23. Paragraph 23 contains legal conclusions to which no answer is required.

24. Paragraph 24 contains legal conclusions to which no answer is required.

25. Paragraph 25 contains legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that TPU filed ANDA No. 211149.

26. Paragraph 26 contains legal conclusions to which no answer is required.

27. Paragraph 27 contains legal conclusions to which no answer is required.

28. Paragraph 28 contains legal conclusions to which no answer is required.

THE PATENT-IN-SUIT

29. Defendants admit that the face of the '906 patent lists the title as "Dosing Regimen Associated With Long Acting Injectable Paliperidone Esters," identifies the assignee as JPN, and that Exhibit A to the Complaint purports to be a copy of the '906 patent. Defendants lack knowledge or information sufficient to form a belief about the truth of the remaining allegations of paragraph 29 a.

30. Defendants admit that the Approved Drug Products with Therapeutic Equivalence Evaluations ("the Orange Book") identifies JPI as the holder of NDA No. 022264 for Invega Sustenna®, paliperidone palmitate extended release injectable suspension. Defendants lack knowledge or information sufficient to form a belief about the truth of the remaining allegations of paragraph 30.

31. Paragraph 31 contains legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit the '906 patent is listed in the Orange Book for Invega Sustenna®.

32. Defendants admit the prescribing information for Invega Sustenna lists treatment of schizophrenia in adults and treatment of schizoaffective disorder in adults as a monotherapy and as an adjunct to mood stabilizers or antidepressants as its indications.

COUNT 1 - INFRINGEMENT OF THE '906 PATENT
BY TEVA'S ANDA FOR INVEGA SUSTENNA®

33. Defendants repeat and incorporate by reference its responses to paragraphs 1-32 of the Complaint.

34. Paragraph 34 contains legal conclusions to which no answer is required. To the extent an answer is required, Defendants do not contest that an actual controversy exists between the parties as to whether sale of TPU's proposed ANDA product infringes at least one claim of the '906 patent.

35. Defendants admit that TPU sent to JPI by letter dated December 5, 2017 ("Paragraph IV Notice Letter") notification that TPU submitted Abbreviated New Drug Application ("ANDA") No. 211149 to the FDA under 21 U.S.C. § 355(j) seeking approval for the commercial manufacture, use, or sale in the United States of Paliperidone Palmitate Extended Release Suspension; 39 mg/0.25 ml; 78 mg/0.5 ml; 117 mg/0.75 ml; 156 mg/ml; 234 mg/1.5 ml (the "Teva ANDA Products") prior to the expiration of the '906 patent.

36. Admitted.

37. Admitted.

38. Defendants admit that TPU attached a memorandum to its Notice Letter in which it alleged factual and legal bases for its paragraph IV certifications, and that the paragraph IV certifications allege that the '906 patent is invalid and/or would not be infringed by the commercial manufacture, use or sale of the drug product described in TPU's ANDA.

39. Admitted.

40. Paragraph 40 contains legal conclusions to which no answer is required.

41. Paragraph 41 contains legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit TPU submitted to the FDA ANDA No. 211149.

42. Paragraph 42 contains legal conclusions to which no answer is required.
43. Paragraph 43 contains legal conclusions to which no answer is required.
44. Paragraph 44 contains legal conclusions to which no answer is required.
45. Defendants admit TPU submitted to the FDA ANDA No. 211149.
46. Paragraph 46 contains legal conclusions to which no answer is required.
47. Paragraph 47 contains legal conclusions to which no answer is required.

PRAYER FOR RELIEF

Defendants deny that Plaintiffs are entitled to any of the relief sought in the prayer for relief or any relief whatsoever.

AFFIRMATIVE AND SEPARATE DEFENSES

First Defense (Failure to State a Claim)

The Complaint fails to state a claim upon which relief can be granted as to TPU.

Second Defense (Failure to State a Claim)

The Complaint fails to state a claim upon which relief can be granted as to TPI.

Third Defense (Non-infringement of the '906 Patent)

The manufacture, use, sale, offer for sale, or importation into the United States of the drug products described in ANDA No. 211149 has not infringed, does not infringe, and will not infringe any valid and enforceable claim of the '906 patent directly, indirectly, by inducement, contributorily, literally, under the doctrine of equivalents, or in any other manner.

**Fourth Defense
(Invalidity of the '906 Patent)**

Each and every claim of the '906 patent is invalid for failure to satisfy one or more provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 101, 102, 103, and 112, and/or is invalid under the doctrine of obviousness-type double patenting.

**Fifth Defense
(No costs)**

Plaintiffs are barred by 35 U.S.C. § 288 from recovering costs associated with this suit.

**Sixth Defense
(Reservation of rights)**

Defendants reserve the right to allege additional affirmative defenses as they become known through the course of discovery.

COUNTERCLAIMS

Without admitting any of the allegations of Plaintiffs other than those expressly admitted herein, and without prejudice of the rights to plead additional Counterclaims as the facts of the matter warrant, Teva Pharmaceuticals USA, Inc. ("TPU") hereby asserts the following Counterclaims against Janssen Pharmaceuticals, Inc. ("JPI") and Janssen Pharmaceutica NV ("JPN") (collectively, "Janssen" or "Plaintiffs").

THE PARTIES

1. Teva Pharmaceuticals USA, Inc. is a corporation organized under the laws of the State of Delaware having a place of business at 1090 Horsham Road, North Wales, Pennsylvania 19454-1090.

2. Upon information and belief, JPI is a corporation organized and existing under the laws of the Commonwealth of Pennsylvania, having its principal place of business at 1125 Trenton-Harbourton Road, Titusville, New Jersey, 08560.

3. Upon information and belief, JPN is a corporation organized and existing under the laws of Belgium, having its principal place of business at Turnhoutseweg, 30, B-2340 Beerse, Belgium.

JURISDICTION AND VENUE

4. This is a declaratory judgment action arising under the patent laws of the United States, Title 35, United States Code. The Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a). The requested relief is authorized by the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

5. Personal jurisdiction over Janssen is proper because, *inter alia*, Janssen initiated and is prosecuting this action, and because, upon information and belief, either directly or through its agents, it transacts business in, and derives substantial revenue from New Jersey.

6. Venue is proper in this Judicial District under 28 U.S.C. §§ 1391 and 1400.

FACTUAL BACKGROUND

7. U.S. Patent No. 9,439,906 (the “’906 patent”) is entitled “Dosing Regimen Associated With Long Acting Injectable Paliperidone Esters,” and states it was issued on September 13, 2016.

8. Upon information and belief, JPN is the owner of the ’906 patent.

9. Upon information and belief, JPI is the holder of New Drug Application (“NDA”) No. 022264 for Invega Sustenna® (paliperidone palmitate) Extended Release Suspension; 39 mg/0.25 ml; 78 mg/0.5 ml; 117 mg/0.75 ml; 156 mg/ml; 234 mg/1.5 ml.

10. The ’906 patent is listed in the Approved Drug Products with Therapeutic Equivalence Evaluations (“the Orange Book”) in connection with NDA No. 022264.

11. TPU submitted Abbreviated New Drug Application (“ANDA”) No. 211149 to the FDA under 21 U.S.C. § 355(j) seeking approval for the commercial manufacture, use, or sale in

the United States of Paliperidone Palmitate Extended Release Suspension; 39 mg/0.25 ml; 78 mg/0.5 ml; 117 mg/0.75 ml; 156 mg/ml; 234 mg/1.5 ml (the “TPU ANDA Products”).

12. ANDA No. 211149 includes a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act that the '906 patent is invalid and/or will not be infringed by the commercial manufacture, use, or sale of the products described therein.

13. TPU sent notice of its certification (the “Paragraph IV Notice Letter”) to JPI on or about December 5, 2017. Upon information and belief, JPI received those notifications.

14. On January 17, 2018, Janssen filed this lawsuit alleging infringement of the '906 patent.

**COUNT I
DECLARATORY JUDGMENT OF INVALIDITY
OF THE '906 PATENT**

15. TPU re-alleges and incorporates by reference the allegations in paragraphs 1-15 of these Counterclaims.

16. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding the invalidity of the '906 patent, based on Janssen's allegation in its Complaint that TPU has infringed or will infringe the '906 patent.

17. Each and every claim of the '906 patent is invalid for failure to satisfy one or more provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 101, 102, 103 and/or 112.

18. TPU notified Janssen in the Paragraph IV Notice Letter that it had submitted the TPU ANDA to the FDA seeking approval to engage in the commercial manufacture, use and/or sale of the TPU ANDA Products prior to the expiration of the '906 patent.

19. The Paragraph IV Notice Letter included a detailed statement of factual and legal bases for the allegation the claims of the '906 patent are invalid.

20. In the Paragraph IV Notice Letter, TPU expressly reserved the right to raise additional non-infringement, invalidity and unenforceability defenses.

21. TPU incorporates by reference the factual and legal bases provided in the Paragraph IV Notice Letter for the allegation that the claims of the '906 patent are invalid.

22. TPU is entitled to a judicial declaration that all claims of the '906 patent are invalid.

COUNT II
DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF THE '906 PATENT

23. TPU re-alleges and incorporates by reference the allegations in paragraphs 1-23 of these Counterclaims.

24. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of the TPU ANDA and/or the manufacture, use, offer to sell, sale, and/or importation into the United States of the TPU ANDA Products infringes, has infringed, or will infringe any valid claim of the '906 patent either directly or indirectly, and either literally or under the doctrine of equivalents.

25. TPU has not infringed, contributed to the infringement of, or induced infringement of any valid claim of the '906 patent either literally or under the doctrine of equivalents. For example, the claims of the '906 patent are invalid for failure to satisfy one or more provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 101, 102, 103 and/or 112. Because one cannot infringe an invalid claim, the claims of the '906 patent are not infringed directly, indirectly, literally, or under the doctrine of equivalents.

26. The Paragraph IV Notice Letter included a detailed statement of factual and legal bases for the allegation the claims of the '906 patent are invalid and thus not infringed.

27. In the Paragraph IV Notice Letter, TPU expressly reserved the right to raise additional non-infringement, invalidity and unenforceability defenses.

28. TPU incorporates by reference the factual and legal bases provided in the Paragraph IV Notice Letter for the allegation that the claims of the '906 patent are not infringed and are invalid.

29. TPU is entitled to a judicial declaration that it has not infringed, contributed to the infringement of, or induced the infringement of the '906 patent either literally or under the doctrine of equivalents, and that the manufacture, use, sale, offer for sale, or importation of the products described in ANDA No. 211149 has not infringed, does not infringe, and will not infringe any valid and enforceable claims of the '906 patent.

COUNTERCLAIM PLAINTIFF'S PRAYER FOR RELIEF

Wherefore, TPU respectfully requests that this Court enter judgment in its favor and against Janssen, and issue an order:

- A. Dismissing Janssen's Complaint with prejudice;
- B. Denying Janssen any of the relief it requested in the Complaint;
- C. Declaring all claims of the '906 patent invalid;
- D. Declaring that the filing of ANDA No. 211149 did not infringe any valid and enforceable claim of the '906 patent;
- E. Declaring that the manufacture, use, sale, offer for sale, and/or importation into the United States of the products described in ANDA No. 211149 would not directly or indirectly infringe any valid and enforceable claim of the '906 patent;
- F. Declaring that the 30-month time period referred to in 21 U.S.C. § 355(j)(5)(B)(iii) be shortened to expire immediately;
- G. Declaring this case exceptional in favor of TPU pursuant to 35 U.S.C. § 285;
- H. Awarding costs and attorneys' fees to TPU; and
- I. Awarding TPU such other and further relief as the Court deems just and proper.

Dated: March 19, 2018

Respectfully submitted,

By: s/Liza M. Walsh

Liza M. Walsh

Christine I. Gannon

William T. Walsh, Jr.

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Attorneys for Defendants

CERTIFICATION PURSUANT TO LOCAL CIVIL RULES 11.2 AND 40.1

Pursuant to Local Civil Rule 11.2 and 40.1, Defendants by their undersigned counsel, hereby certify that to the best of their knowledge, this matter in controversy is not the subject of any other action pending in any court, or of any pending arbitration or administrative proceeding.

Dated: March 19, 2018

Respectfully submitted,

By: s/Liza M. Walsh

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Attorneys for Defendants

CERTIFICATION PURSUANT TO LOCAL CIVIL RULE 201.1

Pursuant to Local Civil Rule 201.1, Defendants by their undersigned counsel, hereby certify that this action seeks declaratory and injunctive relief, and therefore this action is not appropriate for compulsory arbitration.

Dated: March 19, 2018

Respectfully submitted,

By: s/Liza M. Walsh

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